

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN ACADEMY OF PEDIATRICS,
MASSACHUSETTS CHAPTER OF AMERICAN
ACADEMY OF PEDIATRICS, INC.,
AMERICAN CANCER SOCIETY, INC.,
AMERICAN CANCER SOCIETY ACTION
NETWORK, INC., AMERICAN HEART
ASSOCIATION, INC., AMERICAN LUNG
ASSOCIATION, CAMPAIGN FOR TOBACCO-
FREE KIDS, TRUTH INITIATIVE
FOUNDATION, D/B/A TRUTH INITIATIVE,
DR. TED KREMER, DR. JONATHAN
WINICKOFF, and DR. LYNDY YOUNG,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendant.

Civil Action No. 1:16-cv-11985-IT

**ORDER EXTENDING DEADLINE
TO COMPLETE QUANTITATIVE STUDY**

March 21, 2019

TALWANI, D.J.

Before the court is Defendant United States Food and Drug Administration's ("FDA") unopposed Emergency Motion [#58] seeking to extend by 31 days the April 15, 2019, deadline set forth in the court's March 5, 2019, Order Granting Injunctive Relief [#56] for completion of data collection and analysis for FDA's final quantitative study. Defendant's motion is supported by the Declaration of the Mitchell Zeller, Director of the Center for Tobacco Products ("CTF") at the FDA, who reports that: (a) the FDA obtained a control number for the information collection

request (“ICR”) for the final quantitative study from the Office of Management and Budget (“OMB”) on March 8; (b) the independent research institute hired to conduct the study began the study on March 11; (c) the first full day of recruitment of participants began on March 13; and (d) the FDA anticipates that recruitment will take 29 days from that date and will be completed on April 11, 2019. Second Zeller Decl. ¶¶ 5, 11, 13, 17 [#58-2]. Zeller asserts further that the FDA will need to allow 21 days to complete data collection from the last of the participants, and a minimum of 14 days to analyze the data. Id. ¶¶ 19-20.

In light of Zeller’s representation that “even as we do everything in our power to speed the study,” FDA needs until May 16, 2019, to complete the final quantitative study and analysis, id. ¶ 22, the FDA’s representation that it “seeks no additional scheduling extensions in this motion, thus granting this emergency motion will not affect any other deadlines in the Court’s Order” and it “will not seek to extend the [Notice of Proposed Rulemaking] or final rule deadlines based upon th[is] extension,” Mem. at 1-3, and counsel’s representation that Plaintiffs do not oppose the emergency motion, the court EXTENDS the deadline set forth in the Order Granting Injunctive Relief [#56] for completing the final quantitative study to May 16, 2019. The deadlines for the Notice of Proposed Rulemaking and the final rule remain unchanged.

IT IS SO ORDERED.

Date: March 21, 2019

/s/ Indira Talwani
United States District Judge